DVTcare, LLC
731 Construction Ct. Suite B Zeeland, MI 49464

# 510(k) Summary

DVTcare™ CA5

510(k) Number K061125

MAY 23 2006

**Summary Prepared:** Date 12/19/05

**Submitter:**

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**Name of the Device:**

Trade Name: DVTcare™ CA5
Model #: CA5
Common or usual name: Compressible Limb Sleeve Device
Classification Name: Compressible Limb Sleeve
Class II
Product Code: JOW
Regulation No. CFR Part 870.5800
Establishment Registration Number: 3004739895

**Statement of Substantial Equivalence:**

The DVTcare™ CA5 is substantially equivalent to the following commercially available devices:

*WizAir DVT* (510k number: K023573) in that the basis of operation of both devices uses intermittent, pneumatic compression to simulate muscle contractions in the legs aiding the return of venous flow. Compression is achieved by air delivery, through flexible plastic tubing, to inflatable bladders, that are wrapped around the limb(s), to transmit the pneumatic force to the leg. The air delivery is controlled by a microprocessor controlled pump and valve system. Both devices are light weight, portable and can operate on rechargeable batteries alone or while being connected to 110 VAC mains. Indications for use are similar. Cycle operating parameters are similar in pressure delivery and cycle time.

*TravelAir Portable Compression System* (510k number: K022340) in that the basis of operation of both devices uses intermittent, pneumatic compression to simulate muscle contractions in the legs aiding the return of venous flow. Compression is achieved by air delivery, through flexible plastic tubing, that are terminated with CPC quick lock connectors, to inflatable bladders, that are wrapped around the limb(s), to transmit the pneumatic force to the leg. Bladders are composed of PVC. The air delivery is controlled by a microprocessor controlled pump and valve system. Both devices are light weight, portable and can operate on rechargeable batteries alone or while being connected to 110 VAC mains. Indications for use are similar. Cycle operating parameters are similar in pressure delivery and cycle time.

*Venodyne Advantage Plus* (510k number: K011318) in that the basis of operation of both devices uses intermittent, pneumatic compression to simulate muscle contractions in the legs aiding the return of venous flow. Compression is achieved by air delivery, through flexible plastic tubing, to single chamber inflatable bladders, that are wrapped around the lower limb(s), to transmit the pneumatic force to the leg. The air delivery is controlled by a microprocessor controlled pump and valve system that are encased in a molded plastic enclosure. Indications for use are similar. Cycle operating parameters are similar in pressure delivery and cycle time.

*Flowtron Excel AC550* (510k number: K961166) is similar in operation and intended use to the DVTCare CA5. Both incorporate adjustable pressures (between 20mmHg and 65mmHg), single and double leg modes, audible and visual alarms for system monitoring and fault recognition, soft Nylon covered, single chambered garments (cuffs) that wrap around the calf and held in place with hook and loop fasteners.

**Device Description:**

The DVTcare™ CA5 system is a light weight, portable, prescriptive device that helps stimulate blood flow in the legs through the use of pneumatically controlled, single chamber leg cuff(s), actuated by an electronically controlled pump unit and solenoid valves. All pump control unit components are protectively housed in a plastic shell except the outer membrane switch (needed for user interface), 2 plastic quick disconnects for air tube connection, and an external power supply input jack. The option exists for the unit to be used in single leg or double leg modes.

During operation, the pump unit provides air to one cuff through flexible plastic tubing, inflating it to a specified pressure, to compress the lower limb, thus aiding venous return. Air pressure and delivery are monitored by a pressure transducer and integrated system software contained in the plastic control unit. Immediately after the pressure transducer detects that the cuff has achieved the current set pressure, the cuff deflates to ambient pressure. This allows the blood flow to return to the limb. To provide maximum flexibility, the CA5 also provides adjustable cycle times. System software prevents users from entering a cycle time, for any one limb, to be less than 60 seconds. This is done to prevent excessive stimulation of the limb.

In single leg mode, this cycle repeats until the unit is turned off. In double leg mode the first and second leg cuffs do not fill simultaneously. The second leg begins its fill once the first leg has reached the midpoint of the overall cycle time for both legs. In double leg mode, air flow is directed to fill the second bladder cuff using the same cycle profile as the initial leg. After completing the fill, exhaust and rest period of leg 1, the control unit directs air flow to the second leg and fills that bladder cuff until the set pressure is reached and exhausted. The cycle repeats, reverting air flow to the initial leg.

The control unit is supplied with a non-serviceable, rechargeable battery, to allow user portability, and a power supply transformer for mains connection.

**Intended Use:**

The DVTcare™ CA5 is intended to be an easy to use, portable system that is prescribed by healthcare professionals, to help prevent the onset of DVT in patients, by stimulating blood flow in the legs (simulating muscle contractions). Furthermore, the unit can be used as an aid in the prophylaxis for DVT by persons traveling, or those expecting to be stationary for long periods of time (> 4 hours). This device can also be used to: aid in the prevention of DVT, enhance blood circulation, diminish post-operative pain and swelling, reduce wound healing time, and aid in the treatment and healing of: stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency, and reduction of edema in the lower limbs.

**Contraindications:**

The DVTcare™ CA5 should **not** be used to treat the following conditions:

- Persons with suspected, active or untreated: deep vein thrombosis, ischemic vascular disease, severe arteriosclerosis, pulmonary edema, congestive heart failure, thrombophlebitis or an active infection.
- It is not recommended for use on a leg where the cuffs would interfere-with the following conditions: vein ligation, gangrene, dermatitis, open wounds, a recent skin graft, massive edema or extreme deformity of the leg.
- Not for use with patients with neuroapathy.
- Do not use on extremities that are insensitive to pain.
- Do not use where increased venous or lymphatic return is undesirable.
- Leg cuffs are not to be used in direct contact with skin.

**Technological Characteristics:**

The DVTcare™ CA5 is similar to the predicate devices listed above in function and operating principles to achieve identical results however, the CA5 possesses a combination of features that each of the four predicate devices incorporate individually. The CA5 combines these features to offer greater treatment flexibility due to portability, adjustable pressure, and cycle time capabilities. All systems use microprocessor controlled pumps to deliver pressurized air (approximately 40mmHg) to bladders that are attached to the patient's lower limbs, using a cycle of approximately 60 seconds / leg as prescribed by a healthcare provider. Each cycle consists of one inflation (fill time approximately 10-12 seconds) followed by deflation. The CA5 has the capability of allowing a healthcare professional the following feature adjustment options: pressure set point (20-65 mmHg), hold time (0 seconds, not adjustable), cycle time (60-75 seconds). The cycle time is the length of time for one complete cycle on one leg including fill time, exhaust, and idle time (relaxation).

Patient access to these pressure and cycle time adjustments is prevented by requiring the healthcare provider to enter an access code for modification. The unit's default settings are similar to predicate devices in fill time (approximately 10 seconds), pressure (40mmHg), and cycle time (approximately 60 seconds) as noted above.

The CA5 uses similar means for pressure delivery as the predicate devices. Pressurized air is delivered by the pump to the leg cuffs via flexible, plastic air tubes connected to the plastic pump / control unit by locking, quick disconnect couplings. Like the Flowtron Excel, the CA5 leg cuffs are comprised of single bladder PVC chambers encased in a soft Nylon material to increase patient comfort and compliance.

Like the *WizAir DVT* and *TravelAir* the microprocessor and pump units are powered by internal battery supplies and can be connected to the mains power supply for operation and recharging.

**Non-Clinical Testing**

Nonclinical validation including electrical safety, EMC, mechanical integrity, environmental and life cycle testing have shown that the DVTcare™ CA5 has performance characteristics substantially equivalent to or superseding the listed predicate devices. The CA5 has been validated by DVTCare at a design validation level based on the requirements of UL 60601-1, CSA C22.2 NO 601.1 and CENELEC EN 60601-1 and confirmed by an accredited test lab. Being portable, CA5 samples were also tested to MIL-STD 810D, section 514.3-1 for vibrational integrity. Additional bench testing has verified equivalent pressure delivery, cuff (garment) fill time, cycle time and system operation as the predicate devices listed.

**Clinical Testing**

No clinical testing was performed on the DVTCare CA5, however test results of the predicate devices have been compared in the following published clinical studies : *Evaluation of Intermittent Pneumatic Compression Devices* (Orthopedics 24(3):257-261, 2001), and *Venous hemodynamics after total knee arthroplasty: Evaluation of active dorsal to plantar flexion and several mechanical compression devices* (Journal of Bone and Joint Surgery, Nov 1998) . Test subjects for the former study consisted of five healthy individuals aged 21-35 years old and the later consisted of ten patients who were about to have a primary unilateral knee arthroplasty for osteoarthritis. This patient group's mean age was 68 years old with mean weight of 85kg. In summary, the conclusions of each study state that the use of intermittent pneumatic compression devices is useful in decreasing the risk of postoperative DVT. The Venodyne model produced a mean blood flow velocity of 76.2 +/-23.77 using an average pressure of 43mmHg, a compression time of 11.6 seconds and a total cycle time of 60 seconds. These values are extremely similar to corresponding default parameters used by the DVTCare CA5. Since the methods of pressure delivery and operation are identical in both systems, significant equivalence is concluded.

**Summary Conclusion:**

Per the requirements of 21CFR807, surrogate clinical data, non-clinical validation testing and the information provided in the accompanying 510k pre-market submission, Doctor's Orders cocludes that the DVTcare™ CA5 is safe, effective and performs in a manner that is substantially equivalent to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 3 2006

Doctor's Orders, Inc.
c/o Mr. Daniel W. Lehtonen
Intertek Testing Services
2307 East Aurora Road
Twinsburg, Ohio 44087

Re: K061125
DVTcare™ CA5
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: April 21, 2006
Received: April 24, 2006

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K061125

Device Name: DVTCare CA5

Indications for Use: The DVTcare™ CA5 is intended to be an easy to use, portable system that is prescribed by healthcare professionals, to help prevent the onset of DVT in patients, by stimulating blood flow in the legs (simulating muscle contractions). Furthermore, the unit can be used as an aid in the prophylaxis for DVT by persons traveling, or those expecting to be stationary for long periods of time (> 4 hours). This device can also be used to: aid in the prevention of DVT, enhance blood circulation, diminish post-operative pain and swelling, reduce wound healing time, and aid in the treatment and healing of stasis dermatitis, venous stasis ulcers, arterial and diabetic leg ulcers, chronic venous insufficiency, and reduction of edema in the lower limbs.

Prescription Use √ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vo Chmel
(Division Sign-Off)
Division of Cardiovascular Devices



510(k) Number K061125